United Fresh Fruit & Vegetable Association

April 4, 2003

Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Docket No. 02N-0278 RIN 0910-AC41, Prior Notice of Imported Food under the Public Health Security and Bioterroism Preparedness and Response Act of 2002. (68 Federal Register 5428; February 3, 2003); Submission of comments.

Dear Sir or Madam:

The United Fresh Fruit & Vegetable Association (United) is pleased to provide comments on the proposed rule for Prior Notice of Imported Food contained in Docket Number 02N-0278. This rule was developed by the Food and Drug Administration (FDA) to fulfill their obligations set forth by provisions of Title III, Subtitle A, Section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act").

United is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry, promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

Summary of Legislation

United encourages FDA to recognize that the objective of the statutory provision is to provide the Agency with information to facilitate the release of a shipment into commerce within the United States. The general purpose throughout the Act is to determine if credible evidence exists that the food presents a threat of serious adverse health consequences or death to humans or animals. The Public Law No. 107-188 made significant changes to the Federal Food, Drug, and Cosmetic Act and enhanced controls to better protect the safety and security of the United States food supply. Among these changes, Section 307 of the Public Law imposed new requirements upon the importation of food into the U.S. The new import provisions of Section 307 are summarized as follows:

- Amends Section 801 of the FDC Act to require prior notice of imported food shipments. The notice is required to provide the article, the manufacturer and shipper, the grower (if known within the specified time in which notice is required), the country of origin, the country from which the article is shipped, and the anticipated port of entry. If notice is not provided, the article shall be refused admission.
- Requires the Secretary, after consultation with Secretary of the Treasury, to issue regulations that specify the period of advance notice. The advance notice shall be no less than the minimum amount of time necessary for the Secretary to receive, review, and appropriately respond to such notification. The period may not exceed five days.
- Requires the Secretary to promulgate proposed and final regulations by December 12, 2003. If the Secretary fails to meet the deadline, the default period of notice will be no less than 8 hours and no more than five days until the regulation takes effect.
- States that if an article of food is offered for import and prior notice has not been provided, such article shall be held at the port of entry until the importer, owner, or consignee complies. The Secretary, in carrying out this requirement, shall determine whether there is any credible evidence or information indicating that the article presents a threat of serious adverse health consequences or death to humans or animals.
- Amends Section 301 of the FDC Act making it a prohibited act to import or offer for import an article of food in violation of these requirements. Prior to initiating a complex rulemaking, FDA's Center for Food Safety and Applied Nutrition (CFSAN) wisely called for comments from interested parties regarding factors the agency should consider as it proceeds to draft the regulations implementing Public Law No. 107-188.

Introduction

The dramatic impact of the terrorism attacks of September 11, 2001 has led to a new focus in public policy aimed at promoting greater safety and security and preventing terrorist action. As our members provide over 1,000 different fresh fruits and vegetables to American consumers from both domestic growers and around the world, we take our responsibility for prevention, detection, and all necessary actions to protect consumers from intentional contamination of our products seriously.

We encourage FDA to issue regulations that allow flexibility and take into account the produce industry's diversity of products and complexity of global production and distribution. Flexibility is critical in that many prescriptive recommendations would be inappropriate or not applicable to our diverse industry.

We commend the U.S. Food and Drug Administration (FDA) for its leadership in working with the private sector, including our industry, to ensure that appropriate steps are in place to minimize the potential of terrorist action to contaminate foods. However, let us keep in mind the American food supply continues to be the safest in the world. Continuing to ensure the safety and security of fresh fruits and vegetables whether produced domestically or abroad is a top priority of the entire produce industry. With this in mind, we have serious reservations pertaining to certain provisions of FDA's proposed rule for Prior Notice of Imported Food.

Statutory Authority of Prior Notice Information

The proposed rule would require that the prior notice include significantly more information than the Bioterrorism Act requires. The required information far exceeds what is necessary to enable FDA to identify articles of food offered for import that need be inspected. United questions whether FDA has the statutory authority to require the prior notice information outlined in the proposed regulation. The proliferation of data required will take much longer and require considerably more resources than currently necessary to make entry with U.S. Customs. The prior notice proposed rule also enormously increases the paperwork burden by requiring separate notices for every article from different growers. This requirement will result in many more prior notice filings without in any way aiding FDA's ability to identify imports for inspection.

Duplication with Existing Import Regulatory Requirements

In order for the prior notice provision of the Act to achieve its purpose, be workable, and result in the minimal disruption of food importation, processing, and distribution in the United States, a number of factors need to be considered. These factors need to include consistency and seamless integration with existing and pending import notification requirements of the U.S. Customs Service with the goal of minimizing or eliminating unnecessary, multiple or redundant notification. Trade must not be disrupted unnecessarily by the prior notification requirement. FDA's prior notice rule adds duplicative regulatory burdens on importers of food when other federal agencies have similar requirements, namely the U.S. Customs Service and the U.S. Coast Guard.

On October 31, 2002 the U.S. Customs Service issued their final rule (24-Hour Rule) requiring the presentation of vessel cargo declaration to Customs 24 hours before the cargo is laden aboard the vessel at the foreign port. Many of the fourteen data elements required by Customs on the advance cargo manifest are similar to the data requirements outlined in FDA's proposed rule. Customs' 24-Hour Rule primarily applies to the importation of cargo in containers that are shipped by ocean vessels, as carriers of bulk and break bulk cargo can apply for an exemption. Companies that receive an exemption to the 24-Hour Rule must submit their cargo declaration information to Customs 24 hours prior to arrival in the U.S., if they are participants in the Automated Manifest System (AMS), or upon arrival if they are nonautomated carriers.

On February 28, 2003, the U.S. Coast Guard issued their final rules pertaining to the notification of arrival (NOA) at U.S. ports. Again, a complete disclosure of importer and cargo information is required by the Coast Guard. In this case the Coast Guard is requiring importers to file Customs' Cargo Declaration Form 1302 at least 24 hours before arriving at the U.S. port, and 96 hours prior to arrival for vessels on longer voyages.

FDA's rule to receive prior notice information adds another layer of regulatory burden on importers when most of the information required by FDA has already been filed with the U.S. government to meet Customs and Coast Guard requirements. The lack of coordination and

burdensome duplication in the proposed regulation will significantly increase the cost to import produce into the United States. FDA should give greater consideration to coordinating the prior notice requirements with Customs' existing notification and reporting requirements. The efficient operation of ports of entry will require FDA to modify their proposed system for prior notice to accommodate the receipt and acknowledgement of notice on a 24/7 basis. Thus, in order to accommodate acknowledgment of prior notice under a determined time frame, it will be necessary for FDA to increase hours of operations at ports of entry to 24 hours per day, 7 days per week, consistent with those of U.S. Customs.

Grower Information

The proposed rule states that prior notice must include the grower "if known." What if a shipment includes produce from dozens or hundreds of different growers? This requirement is very troublesome. The reporting of grower information may be difficult and burdensome on importers of fresh fruits and vegetables since the number of independent growers on a single shipment can be large. Compliance to this portion of the rule could place great burden on importers of fresh produce since a single shipment of imported produce may come from hundreds of different farms.

The reporting of hundreds of growers and their unique contact information on every prior notice would be a very complex and time-consuming activity, if not an impossible task. FDA suggests that the Prior Notice System "will be developed to accommodate submission of up to three different growers." Clearly this section of the Prior Notice System is not being developed to accommodate the produce industry. The Prior Notice Proposed Rule also enormously increases the paperwork burden by requiring separate notices for every article from a different manufacturer or grower (68 Fed. Reg. at 5435, col. 2.). Such a requirement would result in many more prior notice filings without in any way aiding FDA's ability to identify imports to be inspected. United requests that FDA consider three alternative exemptions related to this requirement, which would alleviate the problems associated with compliance to the reporting of excessive grower information:

- First, in lieu of listing all growers each time of import, the rule could require the filer of the prior notice to have on record the complete list of growers that supply the importing firm with product. The rule could also mandate that this list be provided to FDA upon request.

- Second, an exemption could be granted to filers that make regular imports from a consistent supply source. The regular and consistent occurrence of certain produce imports makes the reporting of grower information on each prior notice an unnecessary requirement.

- Third, an exemption could be granted for the reporting of grower information from small farms. By instituting a small-farm exemption based on acreage amount, the number of growers that would need to be reported on the prior notice could decrease substantially.

We believe that the exemption options outlined above would reduce the redundant burdens that this requirement would cause importers, while having a negligible impact on the intent of the

rule for FDA to screen the safety risks of all imported foods. In addition, we recommend that "unknown" on the notification should be sufficient for FDA's needs and should not trigger a new obligation to inquire for additional information.

Flexibility in Setting Prior Notice Requirements

The import community wishes to aid FDA in its mission of keeping the U.S. food supply safe, pure, and abundant. Prior notice must be submitted by noon of the day before the shipment arrives at the port of entry. For shipments that arrive at 11:59 p.m., this means a nearly 36-hour prior notice. Is such early notice really necessary and is it workable? United believes that for many importers of fresh and highly perishable fruits and vegetables the answer is no. Flexibility in setting minimum notice requirements is necessary because the amount of notice that is feasible to provide this information depends upon the type of goods and the mode of transport. A one-size-fits-all approach in establishing a time period for prior notice is not workable for all shipments crossing our borders. The timeframes for notice, therefore, need to be much more flexible and reflect the current commercial realities and practices of the importing business for these commodities. United represents many firms that import highly perishable fresh produce. These products are particularly susceptible to damage and loss should the import entry procedures lead to lengthy delays in the processing and disposition of shipments. Again, variable time frames should be based on mode of transport, with some consideration given to low-risk importers.

For air transportation, notice should be required on a "wheels up" basis and this will allow FDA anywhere from 1 to 8 hours notice, depending on the departure location, to make decisions concerning inspections. An importer should notify FDA of the shipment at least four hours prior to the plane's estimated time of arrival, or once the plane leaves the ground at the point of departure, and ending with the expiration on the date of importation.

For ocean transportation, we suggest that the notice period be fixed at a four-hour minimum to accommodate the realities of the importation by ocean transportation. Ocean voyages are generally longer, and therefore should accommodate a longer notice period. However, ocean voyages are also potentially subject to great variability and changes in arrival schedules. Weather, mechanical failures and similar problems can significantly delay trans-ocean shipments. Any minimum prior notice needs to be sufficiently flexible to allow for these types of changes in the estimated time of arrival.

Lastly, the appropriate and reasonable period of notice for truck transportation is difficult to determine. Many of the trucks carrying fresh produce from Canada and Mexico to the United States do so from locations that are mere hours from the border. Advance notice is especially unworkable for highly perishable items, such as fresh fruits and vegetables entering the U.S. from Canada and Mexico. Furthermore, a significant percentage of truck traffic from Canada and Mexico into the U.S. involves short journeys, often less than four hours. It is certainly not feasible or reasonable for prior notice to be provided any earlier than the time of departure to the border. United urges FDA to permit importers to comply with the prior notice requirement by presentation of the notice at the border. If, however, FDA demands prior notice of truck shipments from Canada and Mexico, then the agency should consider the following factors:

- FDA should adopt the similar determinations made by the U.S Customs Under the Customs-Trade Partnership Against Terrorism (C-TPAT), in which Customs designates participating importers as "low-risk status," if they have a demonstrated a history of regulatory compliance and supply chain integrity. Thus, participating importers are entitled to expedited processing at the border.

- FDA should permit a shortened notification window for any shipments of highly perishable goods, such as fresh produce.

- FDA should permit a shortened notification window for routine truck shipments that are repetitive and regularly scheduled.

In summary, a workable prior notice system needs to involve a more flexible timing requirement that is not currently reflected in the proposed regulation.

Amendments to Prior Notice Information

The proposed prior notice rule allows filers to amend previously filed notices only under very limited circumstances. A submitter may add additional information about the imported product that was not known at the time the notice was to be submitted. For any changes other than changes to product identity, the submitter must file a new prior notice. The filer must also update the notice if arrival dates and time change. If any of this information is incomplete or inaccurate, the article of food may not enter the United States. Consequently, the accuracy of the many data elements in the notice is crucial. Corrections can not be made for errors in the prior notice, thus the filer must submit a new one. Is this very limited amendment option workable? For the current dynamic and global produce industry, this option is not feasible. Such limited ability to amend will create other enormous paperwork burdens for filers if they are not permitted even to correct minor errors and update changes in information. In the proposed rule, FDA "requests comment on whether changes in quantity will occur after the deadline for prior notice and, if so, how commonly changes occur and how significant the changes usually are." FDA should consider similar measures taken by the U.S. Customs Service in establishing a discrepancy tolerance for quantities of perishable commodities.

The tallying and reporting of piece count and weight can be an inexact exercise for many fresh produce commodities. This requirement is a primary concern that has been expressed to the U.S. Customs Service in response to Customs' implementation of the 24-Hour Rule. To optimize freshness and quality, many agricultural products are harvested, packaged and loaded all right up to the time the ship leaves the foreign port. To meet Customs' new requirements for importing, filers of advance manifests (24 hours prior to loading at foreign port) can only estimate the amount and weight of final packaging from harvests.

Experience to date regarding compliance to Customs' 24-Hour Rule indicates that a range in manifest reporting inaccuracy for product quantity can exist for perishable agricultural commodities from 6% to 15%. Different fresh products require more flexibility than others. Certain produce items have standard weight and box count in the container due to consistency in

packaging. For these commodities, greater accuracy in reporting can be achieved. In contrast, other commodities are packaged in different box sizes. Therefore, more variations from the initial forecasts in box and weight count can be expected for these commodities.

Customs has recognized the uniqueness and difficulty of reporting in advance packaging quantities of perishable merchandise, and has allowed for a "discrepancy tolerance" of 3% for perishable products (see Customs' 24-Hour Rule FAQ document, Item 23). If actual product quantity is within this tolerance range, then no amendment to the manifest is required by Customs. Using a similar discrepancy tolerance may become much more necessary for importers of fresh food using trucks to carry product over land border crossings.

Denial of Entry

If product is detained due to lack of prior notice, how will product be stored? Must trucks and rail cars be off loaded and will there be appropriate facilities for cold storage of highly perishable goods? Product should be held only until prior notice requirements are met and FDA has an opportunity to review and acknowledge. While being held, the product must be stored in appropriate facilities to protect the quality and integrity of the product. This is particularly important for perishable food products, such as fresh fruits and vegetables. United urges FDA to maintain a clear separation between "holding" a product or shipment for failure to provide prior notice and administrative detention. Unless a serious adverse health consequence has been identified, the product should only be held until prior notice requirements have been met and FDA has an opportunity to review and respond. Also, the proposed rule does not provide for a process to appeal denial of entry due to lack of prior notice. United requests clarification from FDA regarding how food companies will proceed in appealing denial of entry. We encourage FDA to communicate clearly to consumers that a violation is due to a failure of a food company not to supply prior notification before importing a food shipment and not because of an inherent food safety or security risk. Lack of adequate communication may result in false food scares and undermine consumer confidence in the agency.

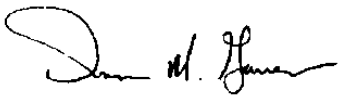
Definition of "Food"

FDA defines food in this proposed rule to include "substances that migrate into food from food packaging and other articles that contact food." In previous interpretations of this statement, namely from the proposed §1.227(c)(4) of the food facility registration rule, FDA clarifies that "'substances that migrate into food from food packaging' include immediate food packaging or components of immediate food packaging that are intended for food use." Does this mean that the import of food contact packaging materials along with the food article, such as plastic lining inside a carton, must also be subject to the prior notice filing requirements? If, by FDA's definition, packaging that contacts food is defined as food under the rule, then it seems that the import of food packaging would require a prior notice in addition to the actual food article. United questions this interpretation for the prior notice rule. Clearly the intent of the prior notice rule is for FDA to receive advance import notice of food articles, not immediate food packaging. FDA should clarify that prior notice is not required for immediate food packaging, just the food article.

Conclusion

In conclusion, United's members strongly support the goal of the Bioterrorism Act to strengthen the safety of our food supply and the efforts by the FDA to implement rulemaking that is consistent with the intent of the law. Perishable fruits and vegetables loose quality, and therefore, market value very quickly. Delays as little as 24 hours can substantially affect value and marketability. Attention must be paid to modifying the proposed regulation to ensure prior notice is integrated with the existing U.S. Customs, Coast Guard, and FDA notice systems. Otherwise, there is a real risk that FDA will be overburdened with redundant and unhelpful notices and will be less able to focus on high-risk importations. Also, if the prior notice system that FDA imposes is not practically achievable, there will be disruptions in the supply of food to consumers and serious trade ramifications with our trading partners. The produce industry is committed to ensuring the security of its products. The industry is proud of the contribution it makes to the health of Americans by providing wholesome foods essential for good health. It is important to always consider that increasing the consumption of fresh fruits and vegetables is a critical component of public health, and that risk management steps are properly weighed with the public health impact on the cost and availability of fresh produce. It is important for the Secretary to keep in mind that the produce industry produces and markets highly perishable items and time is a very valuable commodity. Timely decision-making is critical to the viability of our industry. Thank you for the opportunity to comment. We look forward to continuing to work together with the FDA on these important matters.

Sincerely,



Donna M. Garren, Ph.D.
Vice President, Scientific and Technical Affairs
United Fresh Fruit and Vegetable Association